



90 Orville Drive, Bohemia, NY 11716-2510 ■ Phone: (631) 244-2000 ■ Fax: (631) 218-7480

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Office of Nutritional Products  
Labeling & Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

December 15, 2004

JAN 17 2005

Dear Sir or Madam:

This letter will serve as a 30-day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that NBTY Inc. is using the following statements on our Melatonin supplements under the Rexall and/or Rexall Premium label(s):

- Nighttime Sleep Aid.
- Melatonin works in harmony with your natural sleep cycle to give you the tranquil rest you deserve, and is perfect for people experiencing occasional sleeplessness, those with jet lag, or anyone seeking to improve their quality of rest.

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Angelica S. Vrablic, Ph.D.  
Manager, Nutrition Research

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